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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,837	07/20/2001	Joseph A. Monforte	14-020510US	8812
22798	7590	01/29/2004	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/909,837

**Applicant(s)**

MONFORTE, JOSEPH A.

**Examiner**

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 6,24-29 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-23 and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/24/02  
8/20/02
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 1/5/04
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-35, and species of transcription inducers, proliferative disease, RNA gene product and a broad scanning technique which is microarray analysis in a response filed 10/16/03 and a telephone communication on 1/5/03 is acknowledged.

Claims 6, 24-29 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/16/03.

An action on the merits of elected claims 1-5, 7-23 and 30-35, as they read on the elected species, follows.

***Information Disclosure Statement***

The IDS's filed 4/24/02 and 8/20/02 have been considered in full.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. pages 8, 12, 14, and 18. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16, and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the term “analog” with respect to a compound. The specification does not define the term and there is no specific definition for this term in the art. As one skilled in the art would not know what modifications to a compound would be encompassed by an “analog” to an unspecified compound, the limitations intended by applicant for a compound “analog” are unclear, thus rendering the claim indefinite.

Claim 16 recites “target-specific” modified cell lines and parent cell lines. It is unclear what is intended to be “target-specific”; i.e. the modification, or cell lines. If the latter, then it is unclear which cell lines are intended to be target-specific. Further, it is unclear what is meant by either a “target-specific” modification or “target-specific” cell lines. What target is intended? What (or how) is the modification or cell line “specific” to that target?

Claim 18 recites cell line “optimized” for analysis of a particular disease of interest. It is unclear what is meant by “optimized” with regard to a cell line. One skilled in the art may optimize parameters (e.g. in a model) to better fit experimental data, or may optimize experimental conditions (e.g. to give a better yield). In this context, one skilled in the art may be said to “optimize” cells to provide an “improved” result (e.g. reproduce faster, produce more of particular protein), but one must know what the desired result is in order to get a better one (i.e. to “optimize the result”). One skilled in the art does not generally regard analysis of a disease as a cellular result which may be improved or “optimized”. As it is unclear what limitation of the cells and/or method is intended by cell lines “optimized” for analysis of a disease, claim 18 is indefinite. For purposes of applying the prior art, claim 18 will be interpreted as if it recited any

cells which may be used in analysis of a disease of interest. Claim 19 depends from claim 18 and therefore is also indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-21, 26, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over VAN WOUDE et al. (5,645,988).

Claim 1 recites a method of identifying a composition comprising a desired activity comprising providing a set of compositions, determining a genetic response profile for each member of the set of compositions by (a) providing a plurality of cell lines comprising a parent cell line and at least one cell line modified from the parent cell line such that the modified and parent cell lines differ in either a first or second activity, (b) treating the cell lines with the members of the composition set, and c) detecting responses of the cell lines to the compositions, comparing the responses from steps (a) through c) to the first and second activities of the compositions to determine a pattern of responses correlating to a decrease in the first activity and an increase in the second activity, and screening a second set of compositions for the pattern of responses to identify a new (unknown) composition with the desired activity. Claim 2 limits the modified cell line to differ from the parent in the activity or concentration of a nucleic acid or protein. Claim 3 limits the activity or concentration of a protein of claim 2 to be altered in response to the addition of one or more agents to the parent cell line.

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Claim 4 limits the agent to be one which affects particular DNA or protein activities. Claim 7 limits providing cell lines to performing a genetic selection. Claim 8 limits the cell line to one which is drug resistant. Claim 9 limits the set of compounds to comprise drug compositions identified as treatment agents for the first activity. Claim 10 limits the second activity to comprise an antiproliferative activity. Claim 11 limits the second activity to comprise antineoplastic activity. Claim 12 limits the composition sets to comprise 5-50 compositions. Claim 13 limits the composition sets to comprise 10-20 compositions. Claim 14 limits the composition sets to comprise a compound analog. Claims 15-16 limit the cell lines to particular types. Claim 17 limits the cell lines to comprise 2-10 cell lines. Claims 18-19 limit the cell lines to be "optimized" for a particular disease, specifically proliferative diseases. Claim 20 limits the cell lines to be selected from a recited list. Claim 21 limits the treatment of cell lines to comprise varying concentrations of the compounds, to thereby generate dose-response data. Claim 30 limits the comparing of responses to a comparative analysis of responses and the first and second activities. Claim 33 limits the screening of a second set of compounds to screening a library of compositions. Claim 34 limits the screening of a second set of compounds to determining a genetic response profile. Claim 35 limits the responses collected for the second set of compositions to be a subset of responses collected for the first set.

VAN WOUDE teaches a method of identifying a drug for a desired activity contacting sets of compositions with cancer cell lines, wherein at least one cell line is modified from a parent cell line, a response of the cell lines to the compositions is measured (detected) and wherein a first (observed) activity is growth/proliferation of cancer cells, and a second (desired) activity is inhibition of growth of cancer cells (col. 5, lines 40-50). VAN WOUDE teaches that his inventive method maybe used to identify novel drugs capable of inhibiting the growth of cancer cells, thus suggesting using his screening method to identify new drugs with a desired

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activity (col. 14, lines 28-32). VAN WOUDE teaches that his cells may differ in the presence of absence of a nucleic acid, and teaches that the change in nucleic acid sequence may be introduced using a variety of agents (col. 13, line 10-col. 14, line 27). VAN WOUDE's teaching for genetic alteration (col. 13-14) suggests genetic selection of cell lines for use in his method. VAN WOUDE's teaches that his method can be modified to account for drug resistance cells (col. 42, lines 46-50). VAN WOUDE teaches that concentrations for both 50% inhibition and maximum sensitivity were found (col. 39-40 and Table 6), thus suggesting that dose-response data were obtained. VAN WOUDE teaches that desired activities for his drugs comprise antiproliferative and antineoplastic activities (col. 8, lines 54-65, col. 10, lines 14-15, and Table 4). VAN WOUDE teaches that his cell lines may comprise different cancer cell lines and cells from different tissue types (col. 11, lines 50-53 and col. 12, lines 53-60), teaches that his cell types may include those from the list recited in claim 20 (col. 37, Table 8), and teaches that his cells lines may be modified with specific target diseases and/or drugs in mind (Examples 2 and 3). VAN WOUDE teaches that a set of compositions may comprise 20 potential drugs (col. 43, lines 18-20) and teaches that a plurality of cell lines may comprise six cell lines (col. 43, lines 29-39). VAN WOUDE does not specifically teach a step of screening a second set of compositions for a pattern of responses indicating a desired activity.

It would have been obvious to one of ordinary skill in the art at the time of invention to have screened a second set of compositions for a pattern of activity in order to identify compositions with a desired activity in the method of VAN WOUDE where the motivation would have been to identify drugs which selectively target cancer cells containing an activated oncogene, as taught by VAN WOUDE (col. 42, lines 38-47).

Claims 5, 22-23, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over VAN WOUDE et al. (5,645,988) as applied to claims 1-4, 7-21, 26, and 33-35 above, and further in view of FRIEND et al. (US 6,165,709).

Claim 5 limits the compositions used to modify cells to transcription inducers. Claim 22 limits the detection of responses to a broad-scanning technique to measure the concentration or activity of a gene or gene product. Claim 23 limits the gene product to RNA and the technique to microarray analysis. Claim 31 limits the comparative analysis to graphical representation.

Claim 32 limits the comparative analysis to a variety of analyses.

VAN WOUDE makes obvious a method to identify a compound with a desired activity wherein an agent maybe used to alter the DNA composition of cells, as set forth above. VAN WOUDE also teaches a comparative analysis of his results (Tables 9 and 10). VAN WOUDE does not teach use of transcription inducers to alter cell lines, RNA measurement, graphical representation of data, or any of the comparative analyses of claim 32.

FRIEND teaches a method of drug target screening wherein cells may be modified by changing its transcriptional state (encompassing transcriptional inducers) and RNA abundances may be measured (col. 15, lines 53-63). FRIEND also teaches that perturbations (responses) may be represented as arrays (col. 16, lines 43-45), that a comparative analysis may be graphical (col. 16, lines 45-48), and may include a difference analysis (col. 16, lines 17-25).

It would have been obvious to one of ordinary skill in the art at the time of invention to have include the transcriptional alteration, RNA measurement, and data analysis of FRIEND in the method of VAN WOUDE where the motivation would have been to identify drugs which inhibit growth of particular types of cancer by using specific cancer cell types, as suggested by VAN WOUDE (col. 46, lines 25-38).

**Conclusion**

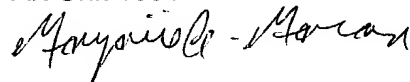
Claims 1-5, 7-23 and 30-35 are rejected; claims 6, 24-29 and 36 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0549.

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631



mam